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OIPE JC67 SEP 11 2003 PATENT & TRADEMARK OFFICE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	09/689,911
Filing Date	Oct 11, 2000
First Named Inventor	Turner, Jr., C. Alexander
Art Unit	1647
Examiner Name	B. Bunner
Attorney Docket Number	LEX-0068-USA

Total Number of Pages in This Submission: 18

ENCLOSURES *(check all that apply)*

- [ ] Fee Transmittal Form
  - [ ] Fee Attached
- [x] Amendment / Reply
  - [x] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request (Original & Copy)
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [x] Appeal Communication to Group ***(Appeal Notice, Brief, Reply Brief)***
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below):*
  - Return Postcard
  - Exhibits A - C

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Lexicon Genetics Incorporated
	Lance K. Ishimoto Reg. No. 41,866
Signature	Lance K. Ishimoto by David W. Hibler DAVID W. HIBLER REG. NO. 41,071
Date	September 5, 2003

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Typed or printed	Michelle Klein	Date	September 5, 2003
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EXPEDITED PROCEDURE
EXAMINING GROUP 1647

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Turner, Jr. *et al.*	Group Art Unit:	1647
Application No.:	09/689,911	Examiner:	B. Bunner
Filed:	10/11/2000	Atty. Docket No.:	LEX-0068-USA

Title: Polynucleotides Encoding Human Galanin Family Proteins (As Previously Amended)

RESPONSE TO OFFICE ACTION DATED MAY 5, 2003

Mail Stop AF
Assistant Commissioner for Patents
Alexandria, VA 22313

Sir:

The Applicants acknowledge the receipt of the Office Action ("the Action") mailed on May 5, 2003 (Paper No. 17), which has been carefully reviewed and studied. Reexamination and reconsideration of the application is requested in view of the following remarks. In order to facilitate the Examiner's evaluation of the application, Applicants have attempted to address the rejections in Paper No. 17 in the same order in which they were originally raised.

A Petition for an Extension of Time of one month to and including September 5, 2003, and authorization to deduct the fee as required under 37 C.F.R. § 1.17(a)(1) from Applicants' representatives Deposit Account are included. The response is thus timely filed. Applicants believe no fees in addition to the fee for the extension of time are due in connection with this response. However, the Commissioner is authorized to charge any additionally required fees or credit any overpayment to Deposit Account No. 50-0892.

RESPONSE

I. Status of the Claims

No claims have been cancelled. No claims have been amended. No new claims have been added.

Claims 1-8 are therefore presently pending in the case. For the convenience of the Examiner, a clean copy of the pending claims is attached hereto as **Exhibit A**.

II. Rejection of Claims 1-8 Under 35 U.S.C. § 101

The Action first rejects claims 1-8 under 35 U.S.C. § 101, as allegedly lacking a patentable utility. Applicants respectfully traverse.

In Applicants' response filed on February 21, 2003 ("response to the Second Action") to the Second Office Action in this case, which was issued on September 24, 2003 ("the Second Action"), Applicants noted that the specification as originally filed indicates that the presently claimed galanin family sequences are involved in a number of functions, including a role in "inflammation" (specification at page 1, line 34). Applicants also pointed out that this phenotype was confirmed in genetically engineered mice that lack the murine homolog of the presently claimed sequence (support for such "knockout" mice can be found, for example, in the specification at page 1, lines 14-15, and page 2, lines 27-28). Knockout mice were created in which a portion of the murine homolog of the presently claimed sequence was deleted. The knockout mice were then subjected to a well known peritoneal inflammation assay, which involves injection of the mice with zymosan, an extract of yeast cells. The homozygous knockout animals showed an increase in total white blood cells compared to a wild-type control, consistent with, as set forth in the instant application, the stated role of this protein in inflammation. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Examiner states that this asserted utility "is credible, but not specific or substantial" (Action at page 3). The Examiner sets forth a number of arguments why Applicants' asserted utility is not "specific or substantial". First, the Examiner states that "(t)he specification does not specifically disclose the generation of knockout mice lacking the murine homolog of the claimed polynucleotide" (Action bridging pages 3 and 4). Applicants respectfully disagree. The specification as originally filed clearly

states that "(t)he invention encompasses ... genetically engineered animals that either lack or over express (*sic*) the disclosed sequences" (specification at page 1, lines 11-15), and that "(t)he invention also encompasses ... transgenic animals that express a NHP transgene, or 'knock-outs' (which can be conditional) that do not express a functional NHP" (specification at page 2, lines 17-28). Thus, the broad class of knockout animals, which by definition includes knockout mice, lacking the orthologous sequence that corresponds to the claimed sequence are clearly supported by the specification as originally filed. Furthermore, that the specification does not specifically single out knockout mice, while potentially relevant to written description questions, is irrelevant to the utility issue at hand. Therefore, the Examiner's argument does not support the alleged lack of utility.

Second, the Examiner states that "(t)he specification also does not disclose subjecting the knockout animals to intraperitoneal inflammation assays to assess the immune system challenge with zymosan" (Action at page 4). Applicants respectfully point out that the zymosan assay is well known to those of skill in the art, having been in use for well over 20 years (see, for example, Barrios *et al.*, Am. J. Pathol. *99*:731-740, 1980; abstract provided in **Exhibit B**). As a matter of law, it is well settled that a patent need not disclose what is well known in the art. *In re Wands*, 8 USPQ 2d 1400 (Fed. Cir. 1988). Therefore, this argument also does not support the alleged lack of utility.

Third, the Examiner argues that "(t)he specification does not teach any diseases or conditions (particularly inflammation) that are associated with a mutated, deleted, or translocated gene of the instant application" (Action at page 4). Once again, Applicants respectfully disagree. The specification as originally filed clearly states that the presently claimed sequence (also referred to in the specification as a NHP) is a galanin protein (see, at least, the specification at page 1, lines 10-11, page 2, lines 5-11, and Section 5.1), that "galanins have been associated with ... inflammation" (specification at page 1, lines 32-33), and, more directly, that "a mutant NHP allele" can result in "a NHP-associated phenotype such as ... an inflammatory disorder" (specification from page 8, line 37 to page 9, line 2). Thus, once again, the Examiner's argument does not support the alleged lack of utility.

Therefore, as the physiological role of the presently claimed sequence in inflammation, as set forth in the specification as originally filed, has been confirmed by Applicants in knockout animals that lack the orthologous sequence corresponding to the claimed sequence, which is clearly supported in the specification as originally filed, the present claims clearly meet the requirements of 35 U.S.C. § 101.

As set forth in *In re Langer* (183 USPQ 288 (CCPA 1974); "*Langer*"):

> As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of § 101 for the entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

Langer at 297, emphasis in original. As set forth in the MPEP, "Office personnel must provide evidence sufficient to show that the statement of asserted utility would be considered 'false' by a person of ordinary skill in the art" (MPEP, Eighth Edition at 2100-40, emphasis added). Thus, absent such evidence from the Examiner concerning the role of the presently claimed sequence in inflammation, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Furthermore, given the obvious medical relevance of the presently claimed sequences, Applicants pointed out in the response to the Second Action that those of skill in the art would readily appreciate the importance of tracking the expression of the genes encoding the described proteins, particularly due to their role in inflammation, as described in the specification as originally filed, at least at page 5, lines 2-4. The Action also questions this utility, stating first that "the claimed polynucleotide is not disclosed as having a specific utility, or having any property ... that can be specifically useful" (Action at page 5). As set forth in detail above, this is clearly not the case. Applicants have clearly asserted that the claimed sequence has a specific role in inflammation, and that the skilled artisan would readily understand that the identification of the physiological role of the claimed sequence in inflammation is certainly useful. The Action goes on to state that "use of the claimed polypeptide (*sic*) in an array for screening purposes is only useful in the sense that the information that is gained from the array is dependent on the pattern derived from the array, and says nothing with regard to each individual member of the array" (Action at page 5). Applicants respectfully point out that nucleic acid sequences have the greatest specific utility in gene chip applications once the role of the sequence has been identified, as in the present case. Once the role of the particular nucleic acid is known, the level of gene expression has and even greater significance. By identifying the physiological role of the claimed sequence, specifically the role of the claimed sequence in inflammation, the claimed sequence has a far greater utility in gene chip applications that just any random piece of DNA. The Action concludes that "this is a utility which (*sic*) would apply to virtually ever (*sic*) member of a general class

of materials, such as any collection of proteins or DNA" (Action at page 5). First, as the physiological role of the presently claimed sequence has been set forth, the present sequence is not just any piece of DNA, as detailed above. Second, the Examiner appears to be confusing the requirement for a **specific** utility, which is the proper standard for utility under 35 U.S.C. § 101, with the requirement for a **unique** utility, which is clearly an improper standard. As clearly stated by the Federal Circuit in *Carl Zeiss Stiftung v. Renishaw PLC*, 20 USPQ2d 1101 (Fed. Cir. 1991; "*Carl Zeiss*"):

> An invention need not be the best or only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: "[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding a lack of utility." *Envirotech Corp. v. Al George, Inc.*, 221 USPQ 473, 480 (Fed. Cir. 1984)

Therefore, just because other nucleic acid sequences find utility in gene chip applications does not mean that the use of Applicants' sequence in gene chip applications is not a specific utility. Furthermore, the requirement for a unique utility is clearly not the standard adopted by the Patent and Trademark Office. If every invention were required to have a unique utility, the Patent and Trademark Office would no longer be issuing patents on batteries, automobile tires, golf balls, golf clubs, and treatments for a variety of human diseases, such as cancer and bacterial or viral infections, just to name a few particular examples, because examples of each of these have already been described and patented. All batteries have the exact same utility - specifically, to provide power. All automobile tires have the exact same utility - specifically, for use on automobiles. All golf balls and golf clubs have the exact same utility - specifically, use in the game of golf. All cancer treatments have the exact same utility - specifically, to treat cancer. All anti-infectious agents have the exact same broader utility - specifically, to treat infections. However, only the briefest perusal of virtually any issue of the Official Gazette provides numerous examples of patents being granted on each of the above compositions every week. Furthermore, if a composition needed to be unique to be patented, the entire class and subclass system would be an effort in futility, as the class and subclass system serves solely to group such common inventions, which would not be required if each invention needed to have a unique utility. Thus, the present sequence clearly meets the requirements of 35 U.S.C. § 101.

Although Applicants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140

USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988)), Applicants detailed in the response to the Second Action that as a further example of the utility of the presently claimed polynucleotides, as described in the specification at least at page 7, line 20, the present nucleotide sequence has a specific utility in determining the genomic structure of the corresponding human chromosome, for example mapping the protein encoding regions. This is evidenced by the fact that SEQ ID NO:1 can be used to map the 5 coding exons on human chromosome 19 (present within Genbank Accession Number AC024580, which is a clone from human chromosome 19; alignment and first page from Genbank record shown in **Exhibit C**). Clearly, the present polynucleotide provides exquisite specificity in localizing the specific region of human chromosome 19 that contains the gene encoding the given polynucleotide, a utility not shared by virtually any other nucleic acid sequences. In fact, it is this specificity that makes this particular sequence so useful. Early gene mapping techniques relied on methods such as Giemsa staining to identify regions of chromosomes. However, such techniques produced genetic maps with a resolution of only 5 to 10 megabases, far too low to be of much help in identifying specific genes involved in disease. The skilled artisan readily appreciates the significant benefit afforded by markers that map a specific locus of the human genome, such as the present nucleic acid sequence. Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

Equally significant is that the claimed polynucleotide sequences define how the encoded exons are actually spliced together to produce an active transcript (*i.e.*, the described sequences are useful for functionally defining exon splice-junctions). The presently claimed sequence clearly identified the intron/exon boundaries, as described above. The specification details that "sequences derived from regions adjacent to the intron/exon boundaries of the human gene can be used to design primers for use in amplification assays to detect mutations within the exons, introns, splice sites (*e.g.*, splice acceptor and/or donor sites), *etc.*, that can be used in diagnostics and pharmacogenomics" (specification at page 7, lines 21-26). Thus, the present claims clearly meet the requirements of 35 U.S.C. § 101.

The Action also questions these asserted utilities, stating that "(s)uch assays can be performed with any polynucleotide" (Action at page 7). The Examiner once again seems to be confusing the requirements of a **specific** utility with a **unique** utility. The fact that a small number of other nucleotide sequences could be used to map the protein coding regions in this specific region of chromosome 19

does not mean that the use of Applicants' sequence to map the protein coding regions of chromosome 19 is not a specific utility (*Carl Zeiss Stiftung v. Renishaw PLC, supra*).

Finally, while Applicants are well aware of the new Utility Guidelines set forth by the USPTO, it has been long established that the current rules regarding the examination of patent applications is and always has been the patent laws as set forth in 35 U.S.C. and the patent rules as set forth in 37 C.F.R., not the Manual of Patent Examination Procedure or particular guidelines for patent examination set forth by the USPTO. Furthermore, it is the job of the judiciary, not the USPTO, to interpret these laws and rules. Applicants point out that guidelines that are not consistent with the patent laws, or the interpretation of these laws by the judicial branch, are not the final word in determining whether or not claims comply with any particular section of the patent laws. Applicants are unaware of any significant recent changes in either 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit that is in keeping with the new Utility Guidelines set forth by the USPTO. This is underscored by numerous patents that have been issued over the years that claim nucleic acid fragments that do not comply with the new Utility Guidelines. As examples of such issued U.S. Patents, the Examiner is invited to review U.S. Patent Nos. 5,817,479, 5,654,173, and 5,552,281 (each of which claim short polynucleotides), none of which contain examples of the "real-world" utilities that seem to be required in the Action. As issued U.S. Patents are presumed to meet all of the requirements for patentability, including 35 U.S.C. §§ 101 and 112, first paragraph (see Section III, below), Applicants submit that the presently claimed polynucleotides must also meet the requirements of 35 U.S.C. § 101. While Applicants understand that each patent application is examined on the basis of its individual merits, Applicants are unaware of any changes to 35 U.S.C. § 101, or in the interpretation of 35 U.S.C. § 101 by the Supreme Court or the Federal Circuit, since the issuance of these patents that render the subject matter claimed in these patents, which is similar to the subject matter in question in the present application, as suddenly non-statutory or failing to meet the requirements of 35 U.S.C. § 101. The requirement of Applicants to meet a different standard of utility in the present case would be arbitrary and capricious, and cannot stand.

For each of the foregoing reasons, as well as the reasons set forth in the response to the Second Action, as well as the reasons set forth in Applicants' response filed on July 1, 2002 to the previous Office Action mailed on April 1, 2002, Applicants submit that as the presently claimed nucleic acid

molecules have been shown to have a substantial, specific, credible and well-established utility, the rejection of claims 1-8 under 35 U.S.C. § 101 has been overcome, and request that the rejection be withdrawn.

III. Rejection of Claims 1-8 Under 35 U.S.C. § 112, First Paragraph

The Action next rejects claims 1-8 under 35 U.S.C. § 112, first paragraph, since allegedly one skilled in the art would not know how to use the invention, as the invention allegedly is not supported by a specific, substantial, and credible utility or a well-established utility. Applicants respectfully traverse.

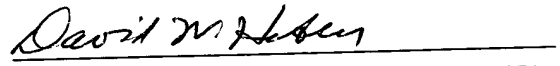
Applicants submit that as claims 1-8 have been shown to have "a specific, substantial, and credible utility", as detailed in section II above, the present rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph, cannot stand.

Applicants therefore request that the rejection of claims 1-8 under 35 U.S.C. § 112, first paragraph, be withdrawn.

IV. Conclusion

The present document is a full and complete response to the Action. In conclusion, Applicants submit that, in light of the foregoing remarks, the present case is in condition for allowance, and such favorable action is respectfully requested. Should Examiner Bunner have any questions or comments, or believe that certain amendments of the claims might serve to improve their clarity, a telephone call to the undersigned Applicants' representative is earnestly solicited.

Respectfully submitted,



September 5, 2003
Date

David W. Hibler Reg. No. 41,071
Agent for Applicants

LEXICON GENETICS INCORPORATED
8800 Technology Forest Place
The Woodlands, TX 77381
(281) 863-3399

Exhibit A

Clean Version of The Pending Claims in U.S. Patent Application Ser. No. 09/689,911

1. (Previously Presented) An isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO: 1.

2. (Previously Presented) An isolated nucleic acid molecule comprising a nucleotide sequence that:

(a) encodes the amino acid sequence shown in SEQ ID NO: 2; and

(b) hybridizes to the nucleotide sequence of SEQ ID NO: 1 or the complement thereof under highly stringent conditions of 0.5 M $NaHPO_4$, 7% sodium dodecyl sulfate (SDS) and 1 mM EDTA at 65°C and washing in 0.1x SSC/0.1%SDS at 68°C.

3. (Original) An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

4. (Previously Presented) An isolated nucleic acid molecule comprising a nucleotide sequence that encodes the amino acid sequence from amino acid number 33 to amino acid number 141 of SEQ ID NO:2.

5. (Previously Presented) A recombinant expression vector comprising the nucleic acid molecule of claim 4.

6. (Previously Presented) The recombinant expression vector of claim 5, wherein the nucleic acid molecule comprises a nucleotide sequence that encodes the amino acid sequence shown in SEQ ID NO: 2.

7. (Previously Presented) The recombinant expression vector of claim 6, wherein the nucleic

acid molecule comprises the nucleotide sequence of SEQ ID NO:1.

8. (Previously Presented) A host cell comprising the recombinant expression vector of claim 5.

App Serial # 09/689,911 * Exhibit B
Turner et al. LEX-0068-USA
Polynucleotides Encoding Human Galanin Family Proteins (As Previously Amended)

Zymosan-induced experimental hypersensitivity pneumonitis in rabbits.

Barrios R, Santos GG, Figueroa J, Reyes PA.

An experimental model of hypersensitivity pneumonitis is presented. New Zealand white rabbits, previously immunized against yeast-derived zymosan, reacted to intratracheal challenge developing extensive pneumonitis. The lesions healed in a few weeks. Control animals challenged with inert particulate material (latex beads) or suspending fluid (PBS-Mg++) did not show pulmonary inflammation. Nonimmunized rabbits developed only transient pneumonitis after zymosan challenge. This reaction was clearly different from that seen in the group of immunized animals. The model reveals that biologically active substances such as zymosan, which is able to activate the alternate pathway of complement and mononuclear phagocytes, requires an active immune state in order to cause significant tissue damage. Isolated exposure to this kind of substance may not be sufficient to cause lung disease.

PMID: 7386601 [PubMed - indexed for MEDLINE]

Query= SEQ ID NO:1
(426 letters)

Sequences producing significant alignments:

	Score (bits)	E Value
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>AC024580.6.1.193609
Length = 193609

Score = 299 bits (151), Expect = 7e-79
Identities = 151/151 (100%)
Strand = Plus / Plus

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NCBI Sequence Viewer

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ACCESSION   AC024580
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  ORGANISM  Homo sapiens
            Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
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REFERENCE   1  (bases 1 to 193609)
  AUTHORS   DOE Joint Genome Institute and Stanford Human Genome Center.
  TITLE     Direct Submission
  JOURNAL   Unpublished
REFERENCE   2  (bases 1 to 193609)
  AUTHORS   DOE Joint Genome Institute.
  TITLE     Direct Submission
  JOURNAL   Submitted (29-FEB-2000) Production Sequencing Facility, DOE Joint
            Genome Institute, 2800 Mitchell Drive, Walnut Creek, CA 94598, USA
REFERENCE   3  (bases 1 to 193609)
  AUTHORS   DOE Joint Genome Institute and Stanford Human Genome Center.
  TITLE     Direct Submission
  JOURNAL   Submitted (13-NOV-2001) DOE Joint Genome Institute, 2800 Mitchell
            Drive, Walnut Creek, CA 94598, USA
REFERENCE   4  (bases 1 to 193609)
  AUTHORS   DOE Joint Genome Institute and Stanford Human Genome Center.
  TITLE     Direct Submission
  JOURNAL   Submitted (21-DEC-2001) DOE Joint Genome Institute, 2800 Mitchell
            Drive, Walnut Creek, CA 94598, USA
COMMENT     On Dec 21, 2001 this sequence version replaced gi:16905144.
            Draft Sequence Produced by DOE Joint Genome Institute
            www.jgi.doe.gov
            Finishing Completed at Stanford Human Genome Center
            www-shgc.stanford.edu
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